2026 Planning & Strategy Questionnaire for Medical Device Manufacturers

Purpose:
This questionnaire audits your expected activities, documentation, language needs, regulatory requirements, and internal capacity for 2026. Your responses will support the creation of your 2026 strategy and operational roadmap.

Section 1: Company Information

1. **Company Name**

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2. **Contact Name**

   _____

3. **Email Address**

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Section 2: 2026 Strategic Plans

4. **What are your main business goals and plans for 2026?**

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   _____
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5. **Do you expect to enter any new markets in 2026?**

   ☐ Yes

   ☐ No

If yes, which ones?

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6. **Are there new internal teams, departments, or key roles planned for 2026? Please describe.**

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Section 3: Products & Submissions

7. **Do you have new products planned for 2026?**

☐ Yes

☐ No

8. **Do you expect new regulatory submissions (e.g., MDR, IVDR, FDA, UKCA, Health Canada) in 2026?**

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9. **Do you expect updated versions of existing products, software, or devices in 2026?**

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Section 4: Documentation Requirements

10. **Which new or updated documentation do you expect to prepare in 2026?**

- ☐ Instructions for Use (IFUs)
- ☐ Labels / Packaging
- ☐ Risk Management Files
- ☐ Clinical Evaluation Reports (CER)
- ☐ Performance Evaluation (PER)
- ☐ SSCP
- ☐ Declarations of Conformity (DoC)
- ☐ Technical Documentation updates
- ☐ Post-Market Surveillance reports
- ☐ Other. Please specify:

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11. **Do you anticipate new versions or updates to existing documentation?**

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Section 5: Language & Localization Needs

12. **Which languages do you expect to require in 2026?**

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13. **Do you expect increased translation volumes in 2026?**

☐ Yes

☐ No

☐ Pretty much the same as last year

☐ Other. Please specify:

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14. **Will you require additional services?**

☐ Regulatory compliance check of already translated materials (MDR/IVDR, EMA, FDA)

☐ Clinician review or in-country review of already translated materials

☐ QA report generated after the updates

☐ PDF Accessibility Services

☐ User Interface (UI), Graphic User interface (GUI) Electronic Implementation

☐ in-App / in-Context review after Electronic Implementation

☐ Readability / Usability testing (IFUs, PILs, patient-facing content)

☐ Linguistic Validation (COAs, patient-facing content)

☐ Cognitive Debriefing (COAs, patient-facing content)

☐ EMA QRD Template translation and updates of (SPCs, PILs, labeling)

☐ Certificate of Translation

☐ Declaration of Conformity translation

☐ Translation Evidence Packages for audits

☐ Consultancy on translation and linguistic best practices for medical device manufacturers and regulators

☐ Webinars on translation and linguistic best practices for medical device manufacturers and regulators

☐ None

☐ Not sure — please advise

☐ Other. Please specify

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Section 6: Regulatory Requirements

15. **Which laws, standards, and conventions do you need to adhere to in 2026?**

☐ MDR / IVDR

☐ ISO standards (specify which: ISO 13485, ISO 14971, ISO 15223-1, etc.)

☐ IEC standards

☐ National/local market regulations

☐ UDI requirements

☐ Labeling conventions for new markets

☐ Other. Please specify:

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16. **Are there any upcoming regulatory deadlines or timeframes you must meet in 2026?**

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Section 7: Internal Team & Stakeholders

17. **Who will be the key internal people involved in product updates, documentation, translations, and submissions in 2026?**

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18. **Will you require external support (e.g., project management, translation management, regulatory consulting)?**

☐ Yes

☐ No

If yes, what areas would you like us to support or fully manage? In addition to content solutions and language consultancy, we work closely with regulatory and compliance companies, legal advisors, marketing specialists, and a network of distributors, so we can support you and help you find the right solution.

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Section 8: Workshop Topics to Cover

19. **Which topics would you like us to cover during the 20 January Strategy Workshop?** *(Select all that apply)*

☐ 2026 documentation planning (Helps you map expected document updates, new submissions, and multilingual requirements for the coming year)

☐ MDR/IVDR language readiness (Assessing where you stand with regulatory language obligations and identifying gaps for 2026)

☐ IFU and labeling language updates (Planning updates to Instructions for Use, packaging, leaflets, patient materials, and device labeling)

☐ Language, translation & localization strategy (Defining a structured approach to multilingual compliance, market expansion, and workflow optimization)

☐ How to work effectively with language service providers (LSPs) (Best practices for communication, timelines, quality expectations, and regulatory alignment with LSP partners)

Section 9: Additional Notes

20. **Is there anything else you'd like us to know about your 2026 planning?**

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If you would like to share your questionnaire replies with us, please contact us using the QR code below. It contains our full contact details for your convenience.